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Attorneys for Defendants
RESHAPE MEDICAL LLC and
RESHAPE LIFESCIENCES, INC.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

FULFILLIUM, INC.,

Plaintiff,

v.

RESHAPE MEDICAL LLC and
RESHAPE LIFESCIENCES, INC.

Defendants.

RESHAPE MEDICAL LLC and
RESHAPE LIFESCIENCES, INC.

Counter-Plaintiffs,

v.

FULFILLIUM, INC.,

Counter-Defendant.

Case No. 8:18-cv-01265-RGK-PLA

DEFENDANTS' NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT ON NON-INFRINGEMENT

Date: August 12, 2019
Time: 9:00 a.m.
Place: Courtroom 850, 8th Floor
Judge: Hon. R. Gary Klausner

TO: ALL PARTIES AND THEIR COUNSEL OF RECORD

PLEASE TAKE NOTICE that on Monday, August 12, 2019, at 9:00 a.m., or as soon thereafter as counsel may be heard, in Courtroom 850 of the Roybal Federal Building and United States Courthouse, located at 255 East Temple Street, Los Angeles, CA 90012, Defendants ReShape Medical, Inc. and ReShape Lifesciences, Inc. ("ReShape") will and hereby do move this Court to enter summary judgment on non-infringement against Plaintiff Fulfillium, Inc. ("Plaintiff" or "Fulfillium"). Specifically, ReShape moves for an order granting summary judgment in its favor on (1) Plaintiff's Count II, alleged infringement of U.S. Patent No. 9,456,915, and on ReShape's Counterclaim 1, declaratory judgment on non-infringement of U.S. Patent No. 9,456,915; (2) Plaintiff's Count III, alleged infringement of U.S. Patent No. 9,445,930, and on ReShape's Counterclaim 2, declaratory judgment of non-infringement of U.S. Patent No. 9,445,930; and (3) Plaintiff's Count IV, alleged infringement of U.S. Patent No. 9,808,367, and on ReShape's Counterclaim 3, declaratory judgment of non-infringement of U.S. Patent No. 9,808,367.

This Motion is and will be based upon this Notice of Motion, the accompanying Memorandum of Points and Authorities in support thereof, the accompanying Separate Statement of Uncontroverted Facts and Conclusions of Law, and the accompanying Declarations of Janel Dirk and Archana Nath.

This Motion is made following a conference of counsel on July 1, 2019, pursuant to Local Rule 7-3.

Dated: July 9, 2019

Respectfully submitted,

FOX ROTHSCHILD LLP

By: */s/ Larina A. Alton*
Larina A. Alton (*Pro Hac Vice*)

Attorneys for Defendants
RESHAPE MEDICAL, INC. and
RESHAPE LIFESCIENCES, INC.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Fulfillium asserts that ReShape has infringed three of its patents: USPN 9,456,915 ("the '915 Patent"), USPN 9,445,930 ("the '930 patent"), USPN 9,808,367 ("the '367 patent") (collectively, the "Patents-In-Suit"). (Nath Decl. Exs. A–C.) Specifically, Plaintiff asserts that ReShape's Dual Balloon/Duo Balloon ("Accused Device" or "Duo Balloon")) infringes Claims 1–2, 4–11, 19–23, and 25–30 of the '915 patent, Claims 1–2, 4–11, 19–30 of the '930 patent, and Claims 1, 4–7, 11–12, 16–21 of the '367 patent ("Asserted Claims"). (Nath Decl. Ex. D at Exs. A–C to Interrog. Resp. 8.) ReShape denies those allegations and submits this summary judgment motion on non-infringement as to each Asserted Claim.[1]

II. BACKGROUND

A. The Patents-in-Suit.

Each of the Patents-in-Suit are in the same patent family and share the same or similar disclosure. (Birk Decl. ¶ 6.) The alleged invention of the Patents-in-Suit relates to a medical device for obesity weight loss. (*See, e.g.*, Nath Decl. Ex. B, at 1:22–24; Birk Decl. ¶ 6.) Specifically, the alleged invention relates to an inflatable implant deployed into the gastric cavity of a patient to assist in creating a feeling of fullness in order to help the patient eat less. (Birk Decl. ¶ 6.) Gastric balloons comprise one or more compartments, "typically inflated with saline or other non-toxic materials," that take up space within the gastric cavity of a patient. (Nath Decl. Ex. B, at 2:36–41; Birk Decl. ¶ 7.) The Patents-in-Suit disclose several embodiments of the gastric balloon. In each embodiment, the gastric balloon "include[s] at least two

[1] This motion relies upon the Separate Statement of Uncontroverted Facts and Conclusions of Law, Declaration of Archana Nath ("Nath Decl."), the Declaration of Janel Birk ("Birk Decl."), and the exhibits thereto. The elements of the asserted claims are provided and lettered in the Appendix to the Birk Decl.

principal structural components[:]" (1) "an expandable scaffold which helps define a shape conforming to a gastric cavity, typically a crescent or 'kidney' shape, when expanded, and (2) one or more inflatable or otherwise expandable space-occupying structures or compartments which are secured to the interior and/or exterior of the expandable scaffold." (Nath Decl. Ex. B, at 9:8–39; Birk Decl. ¶ 7.) The balloon structure's scaffold, which creates the "crescent or 'kidney' shape," may be used "to align the balloon wall against the greater and lesser curvatures of the stomach." (Nath Decl. Ex. B, at 9:2–4; Birk Decl. ¶ 7.)

For example, as seen in FIG. 8 and cross-sectional view FIG. 9, reproduced below, the gastric balloon 10 includes a crescent or kidney shaped scaffold 12, one or more inflatable space-filling compartments 14, and one or more inflatable external bladders 16. It may further include an upper and/or lower cage 18, 20 to permit tools to grasp the gastric balloon 10. (Nath Decl. Ex. B, at 17:61–18:11; Birk Decl. ¶ 8.)

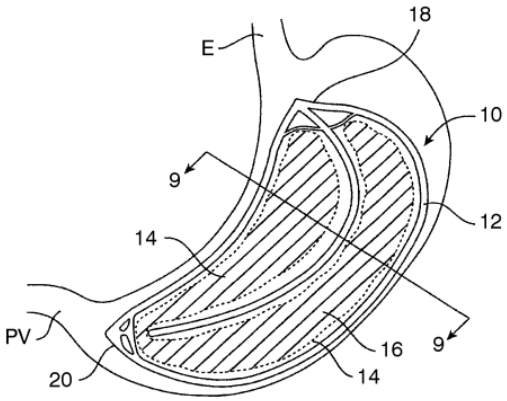


FIG. 8

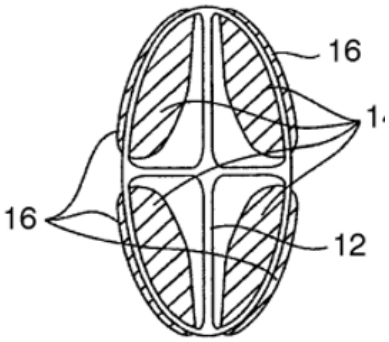


FIG. 9

The inflatable compartments may be connected or held together using a spine (element 1512 in FIG. 15A or element 1550 in FIG. 15F, reproduced below.) (Birk Decl. ¶ 9.) The spine may be made from "elastic components, such as nickel titanium alloys or other super elastic materials, permitting them to be folded and compressed to a small width for introduction." (Nath. Dec. Ex. B, at 20:51–47; Birk Decl. ¶ 10.)

The spine may be used to receive and deploy inflation tubes and/or may be inflatable itself. (*Id.* at 21:1–5, 21–29.)

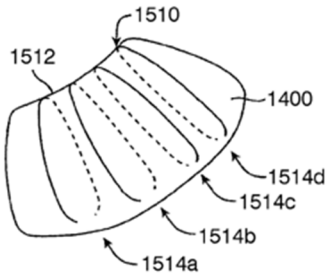


FIG. 15A

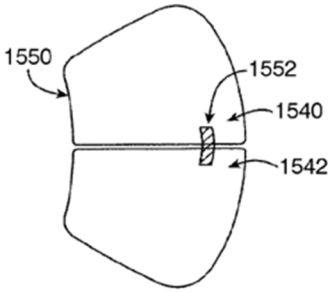
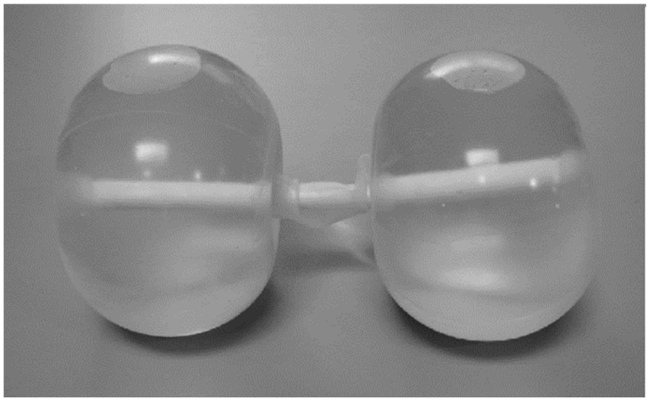
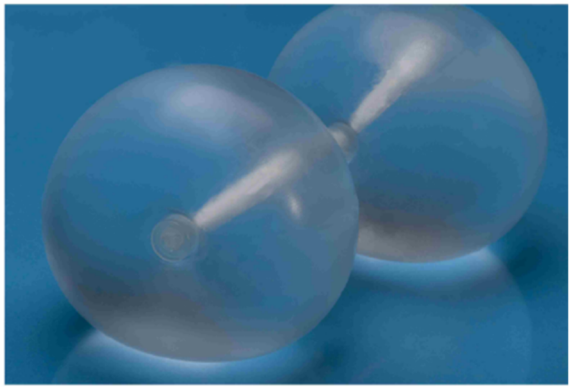


FIG. 15F

B. The Accused Product.

The ReShape Duo Balloon ("Duo Balloon") is a non-surgical obesity treatment device. (*See, e.g.*, Nath Decl. Ex. M, at RESHAPE0038557.) It is a gastric balloon system that is inserted into a patient's stomach and inflated to occupy existing space in the stomach for up to six months. (*Id.* at RESHAPE0038558; Birk Decl. ¶ 4.) The Duo Balloon has a dual balloon design where two inflatable balloons are connected by a shaft:





(Birk Decl. ¶ 4; Nath Decl. Ex. O, Youngstrom Dep. 98:17–20, 99:13–16.) When inserted into a stomach, the Duo Balloon is filled with a maximum of 900cc of saline—450cc in each balloon—which occupies more space than the 400-700cc fill-volume typical of single balloon gastric devices. (Nath Decl. Ex. M, at RESHAPE0038558; Birk Decl. ¶ 4.) By filling space in the patient's stomach with

the Duo Balloon, the patient feels full and satisfied with less food, thereby providing a portion-control function. (Nath Decl. Ex. M, at RESHAPE0038558; Birk Decl. ¶ 5.)

III. LEGAL STANDARDS

A. Summary Judgment Standard.

"Summary judgment is as appropriate in a patent case as in any other." *Barmag Barmer Maschinenfabrik AG v. Murata Mach., Ltd.*, 731 F.2d 831, 835 (Fed. Cir. 1984). The moving party bears the initial burden of identifying those portions of the pleadings, discovery, and affidavits that demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). Once the moving party meets its initial burden, the nonmoving party must set forth, by affidavit or other evidence, "specific facts showing that there is a genuine issue for trial." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986). The "mere existence of a scintilla of evidence" in support of the nonmoving party's position is insufficient; there must be "evidence on which the jury could reasonably find" for the nonmoving party. *Id*. at 252. If the non-moving party fails to produce enough evidence to show a genuine issue of material fact, "the moving party is entitled to a judgment as a matter of law." *Celotex Corp.*, 477 U.S. at 322–23.

B. Summary Judgment on Patent Infringement.

There are two types of direct infringement: (1) literal infringement, and (2) infringement under the doctrine of equivalents. "To infringe a claim, each claim limitation must be present in the accused product, literally or equivalently." *Dawn Equip. Co. v. Ky. Farms, Inc.*, 140 F.3d 1009, 1014 (Fed. Cir. 1998) (emphasis added). Thus, "[a] patentee claiming infringement must present proof that the accused product meets each and every claim limitation." *Forest Labs., Inc. v. Abbott Labs.*, 239 F.3d 1305, 1310 (Fed. Cir. 2001) (citations omitted) (emphasis added). The absence of one claim element establishes non-infringement. *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991).

Under the doctrine of equivalents ("DOE"), "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Company, Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 21 (1997) (citation omitted). The Federal Circuit has cautioned against impermissible broadening when performing an equivalence analysis: "It is the role of the court . . . to ensure that the doctrine of equivalents is not permitted to overtake the statutory function of the claims in defining the scope of the patentee's exclusive rights." *Deere & Co. v. Bush Hog, LLC*, 703 F.3d 1349, 1356 (Fed. Cir. 2012) (citation omitted).

A party may also be liable for indirect infringement, either by actively inducing infringement or by contributing a component constituting a material part of the invention. 35 U.S.C. § 271(b)–(c). To be liable for inducing infringement, the inducer must have had actual knowledge its acts constituted infringement. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011); *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 843 F.3d 1315, 1332 (Fed. Cir. 2016). To be liable for contributory infringement, the contributor must have had knowledge that its component was made/adapted for use in infringing the patented invention and that it was not suitable for any "substantial noninfringing use." 35 U.S.C. § 271(c). Any claim of indirect infringement requires a threshold finding of direct infringement. *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 917 (2014).

IV. ARGUMENT

A. Person Of Ordinary Skill In The Art.

A person of ordinary skill in the art at the time of the invention ("POSA") during the relevant timeframe would have been a person with at least a bachelor's degree in mechanical engineering and at least three to five years of experience in mechanical design aspects of medical products. A POSA during the relevant

timeframe, additionally or alternatively, could have been a person with a medical doctorate degree and at least one to two years of experience in medical product design. Based upon her education and experience, Reshape expert Janel Birk would qualify as at least a POSA in the relevant time frame. (Birk Decl. ¶ 5.)

B. Claim Construction.

"Claim construction requires a determination as to how a POSA would understand a claim term in the context of the entire patent, including the specification." *Trs. of Columbia Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1362 (Fed. Cir. 2016) (quotation omitted). In district courts, a claim must be given its plain and ordinary meaning as would have been given by a POSA at the time the patent application was filed. *See, e.g., On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d 1331, 1344 (Fed. Cir. 2006). When readily apparent, claim construction involves little more than accepting the meaning of commonly understood words. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). However, where not readily apparent, intrinsic and then extrinsic evidence may be used to discern the meaning of the term. *Id*. at 1314–24.

Intrinsic evidence includes "the claim language itself, the specification, and the prosecution history." *Alza Corp. v. Mylan Labs., Inc.*, 391 F.3d 1365, 1370 (Fed. Cir. 2004). After considering intrinsic evidence, courts may consider extrinsic evidence to construe relevant claims. *See Phillips*, 415 F.3d at 1317–18. Specifically, extrinsic evidence consists of "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Cont'l Circuits LLC v. Intel Corp.*, 915 F.3d 788, 799 (Fed. Cir. 2019) (citation omitted).

Despite ReShape's repeated requests, Plaintiff never provided its proposed claim constructions of relevant claim terms, other than for asserted means-plus-function claims, during fact discovery. (*See* Nath Decl. Ex. D, at Interrog. Resp. 12.) Instead, Plaintiff has merely stated that it will rely upon the "plain and ordinary"

meaning of claim terms. (*Id.*) Moreover, due to issues that arose at the end of discovery, the parties mutually agreed to delay expert reports and to request a summary judgment scheduling extension of one week from the Court. The stipulation was not granted, and the parties are therefore in the mutual position of not having one another's expert reports as of the date of this filing. Regardless, the scheduling order provided for rebuttal expert reports after the motion deadline. As such, ReShape does not have Plaintiff's claim construction positions through expert discovery either. However, for the purposes of this motion, ReShape infers what it can of Plaintiff's claim construction from Plaintiff's infringement charts. Relevant claim constructions are discussed below as they arise in discussions of non-infringement.

C. Plaintiff's Indirect Infringement Claim Fails.

In order to make an indirect infringement claim, Plaintiff must show induced or contributory infringement. For inducement, Plaintiff must show that a third party directly infringed, ReShape induced those infringing acts, and ReShape had actual knowledge that its acts constituted infringement. *Global-Tech Appliances, Inc.*, 563 U.S. at 766; *Power Integrations, Inc.*, 843 F.3d at 1332; *Ondeo Nalco Co. v. EKA Chemicals, Inc.*, No. Civ. A. 01-537-SLR, 2002 WL 1458853, at * 1 (D. Del. June 10, 2002) (dismissing "vague" claim of induced infringement that failed to allege direct infringement by a party other than the accused inducer). Plaintiff's infringement charts attached to its interrogatory response contain no reference to indirect infringement. (Nath Decl. Ex. D, at Exs. A–C to Interrog. Resp. 8.) Although the text of Plaintiff's interrogatory response provided on the last day of discovery does reference ReShape having "induced infringement," Plaintiff only generally states that ReShape has done so by having "directed and/or instructed physicians on how to use, install, and operate" the Accused Device. (*See* Nath Decl. Ex. D, at 2nd Supp. Interrog. Resp. 8.) Besides, as discussed *infra* with respect to physicians and *infra* with respect to the claim elements, there is no direct infringement, which is required

for a finding of indirect infringement. *Limelight Networks*, 572 U.S. at 917.

Similarly, Plaintiff's interrogatory response alleges that ReShape "directly infringed" the Patents-in-Suit "by forming a joint enterprise with the hospitals and/or doctors that use the Accused Devices" and "by conditioning use of the Accused Devices on the instructions of use provided therewith, which instructions instruct the doctors and/or hospitals on how to use the Accused Devices in a way that infringes the patents-in-suit." (See Nath Decl. Ex. D, at 2nd Supp. Interrog. Resp. 8.) Instructing another person to perform an act constituting infringement is an indirect infringement, not a direct infringement claim. *See Global-Tech Appliances, Inc.*, 563 U.S. at 760–61 (2011).

D. Plaintiff's Direct Infringement Claim Under the Doctrine of Equivalents Fails.

Plaintiff's infringement charts attached to its interrogatory response contain no reference to DOE at all. (Nath Decl. Ex. D, at Exs. A–C to Interrog. Resp. 8.) Although the text of Plaintiff's interrogatory response does reference DOE, Plaintiff only generally refers to two DOE arguments: (1) a flapper valve being the equivalent of a valve, and (2) the shape of the device being the equivalent of a kidney shape. (*See* Nath Decl. Ex. D, at 2nd Supp. Interrog. Resp. 8.) This vague DOE assertion, particularly without any detail as to how aspects of the Accused Device satisfy either of the DOE tests articulated above, is insufficient under the law and entitles ReShape to summary judgment on direct infringement under DOE. *See, e.g., Texas Instruments, Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1567 (Fed. Cir. 1996) ("Generalized testimony as to the overall similarity between the claims and the accused infringer's product or process will not suffice [to show infringement under the doctrine of equivalents]."); *Lear Siegler, Inc. v. Sealy Mattress Co. of Michigan, Inc.*, 873. F.2d 1422, 1425 (Fed. Cir. 1989) ("[S]ubstantial identity must be proven with regard to all three elements of the doctrine specified in *Graver Tank*: *function*

performed, *means* by which the function is performed, and *result* achieved. . . . The evidence and arguments [on DOE] cannot merely be subsumed in plaintiff's case of literal infringement."). Thus, the Court should grant ReShape's motion as to direct infringement under DOE.

E. Plaintiff's Direct Infringement Claim Fails Because It Requires a Human Stomach.

Plaintiff contends that "[t]he reference to the 'kidney shape' in the patents-in-suit generally refers to the shape of the ***stomach*** not the device." (Nath Decl. Ex. D, at 2nd Supp. Interrog. Resp. 8.) In essence, Plaintiff asserts that the claims referring to a "kidney shape" encompass a stomach. But a stomach cannot be claimed pursuant to Sections 101 and 112. *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat 340 (2011). Indeed, under the law, "no patent may issue on a claim directed to or encompassing a human organism." *Id.* (note to 35 U.S.C. § 101). Regardless, ReShape does not put any devices into stomachs. According to Fulfillium, the device does not infringe until it is placed into a stomach. Therefore, it is impossible to contend that ReShape directly infringes any of the asserted claims.

F. Plaintiff's Direct Infringement Claims Fail Because the Accused Product Does Not Infringe the Asserted Claims.

Even if the Court were to consider Plaintiff's infringement claims, ReShape is entitled to summary judgment because it does not infringe any Asserted Claim. While ReShape contests alleged infringement of all Asserted Claims, for purposes of summary judgment, ReShape focuses on the Asserted Independent Claims:

Patent	Asserted Independent Claims
'915	Claims 1 and 19
'930	Claims 1 and 19
'367	Claims 1 and 16

Infringement claims relating to the Asserted Dependent Claims fail because those claims depend on the Independent Claims.[2] *See Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1316, n.1 (Fed. Cir. 2006).

Set forth below is an analysis of claim elements not met by the Duo Balloon. The elements are grouped by similar structural language claimed in all three Patents-in-Suit. ReShape uses this format not only because the language is similar across Patents but, as to all claim terms for the Patents-in-Suit other than means-plus-function claims, Plaintiff has never provided proposed claim constructions of relevant claim terms. (Nath Decl. Ex. D, at Interrog. Resp. 12.) Despite repeated requests for this information during discovery, Plaintiff has asserted only that it will rely on the plain and ordinary meaning. Moreover, Plaintiff relies on the same evidence to support its infringement contentions for all similar claim elements across the Patents-in-Suit. (*See* Nath Decl. Ex. D, at Ex. A–C to Interrog. Resp. 8.) Additionally, all three patents share the same specification and Figures. As such, the same terms across Patents should have the same meaning.

1. The Duo Ballon Does Not Have A Structure With A Curved Shape Conforming To A Kidney Shape.

Claim 1 of all three Patents-in-Suit (and the depending claims) claims an obesity treatment device or gastric balloon structure, in an inflated or partially inflated state, that "assumes" or "forms" "a curved shape conforming to a natural three-dimensional kidney shape" of the stomach or gastric cavity. (*See* Nath Decl. Ex. A, at Claim 1e; *id.* Ex. B, at Claim 1e; *id.* Ex. C, at Claim 1f (emphasis added); *see also id.* Ex. A, at Claim 8b.) Independent Claim 19 of the '915 Patent also claims "a means for conforming a flexible, space-filling structure to a natural kidney shape of a gastric cavity in a patient." (Nath Decl. Ex. A, at Claim 19b (emphasis added).) Claim 19

[2] ReShape's Duo Balloon also fails to practice each of the claimed elements in the Asserted Dependent Claims and therefore do not infringe any Asserted Claim.

of the '930 Patent claims "a means for occupying an overall space-filling geometry having or conforming to a natural kidney shape of the stomach, upon inflation." (Nath Decl. Ex. B, at Claim 19b (emphasis added).) (*See also* Birk Decl. ¶ 11.)

The Plaintiff apparently asserts that this claimed structure refers to a device that is *first inserted into the gastric cavity*. Plaintiff has also taken the position that each claim referring to a curved, crescent, or kidney shape refers only to the shape of the *stomach*, rather than the device. (*See* Nath Decl. Ex. D, at Ex. A–C to Interrog. Resp. 8.) As such, it appears to be the Plaintiff's view that the device need only be made of a flexible material that will *fit* inside a stomach, which is kidney shaped. (*See id.*). (*See* Nath Decl. Ex. D, at 2nd Supp. Interrog. Resp. 8, 12; *see id.* Ex. E, Chen Dep. at 211:14–22 (testifying that "[i]t's not the shape when it's alone outside of the body. What matters is what's inside the body").)

But the Claims do not support such a position.[3] First, nothing in the Claim language or specification requires that the device be inserted into the stomach to meet the limitation. The Claims do not say the balloon conforms to a kidney shape "when inserted into a gastric cavity." Instead, they say that it assumes a curved shape conforming to a kidney shape when the device is "inflated" or at least "partially

[3] Indeed, this reading would render claim language superfluous. Each of the claims require *separately* that the balloon must both assume a shape upon inflation *and* that the edges of the device must be in parallel with the gastric cavity. Elements 1f of the '915 and 930, and element 1g of the 367 (everything that follows "such that,") would have no meaning under Fulfillium's construction. Claim 1 of both the '915 Patent and the '367 Patent claim a flexible member or flexible spine that "flexibly conforms, upon at least partially filling the at least two isolated non-concentric inflatable chambers, the gastric balloon structure of the natural three-dimensional kidney shape of the gastric cavity." (Nath Decl. Ex. A, at Claim 1f; *id.* Ex. C, at Claim 1g.) "Conform" means to have or take on the same shape or outline. (Birk Decl. ¶ 15.)

inflated." (Birk Decl. ¶ 13.) Plaintiff is attempting to read an element into the Claims that does not exist. Nor would such an element requiring a stomach be permissible under section 101, as set forth above in Section IV.E. Thus, to meet this element in the relevant Claims of each Patent-in-Suit, the Duo Balloon must itself (regardless of whether it is inserted into the stomach) have a curved shape that conforms to a kidney shape upon inflation or partial inflation. (Birk Decl. ¶ 13.)

Second, the Claim language requires more than the structure merely being flexible enough to fit into a gastric cavity. The limitations expressly require the device to assume, form, or have a curved shape "conforming to" a kidney shape. (*Id.* ¶ 14.) "Conform" means to have or take on the same shape or outline. (*Id.* ¶ 15.) *See Protective Indus. Inc. v. Ratermann Manuf. Inc.*, 920 F. Supp. 2d 868, 872, 876–77 (M.D. Tenn. 2013) (construing "conform" to mean "having a shape substantially the same shape [as]" and finding no infringement because a rectangular-shaped face does not have substantially the same shape as a bell-shaped face).) A "kidney shape" is defined as a "crescent shape geometry" or "having the general shape of a long oval indented at one side." (Birk Decl. ¶ 16.) *Casler v. U.S.*, 9 U.S.P.Q.2d 1753, 1772 (U.S. Ct. Cl. 1988) (adopting Random House Dictionary definition of an indented oval)

The specification supports this reading, disclosing that the balloon may have a "crescent or 'kidney' shape to align the balloon wall against the greater and lesser curvatures of the stomach. . . ."[4] (Nath Decl. Ex. A, at 9:2–4; *id.* Ex. B, at 9:2–4; *id.* Ex. C, at 9:21–23.) The following embodiments of the Patents-in-Suit are each kidney

[4] As one of the inventors of the Patents-in-Suit testified, "greater and lesser curvatures" "refer[s] to the kidney shape of the stomach." (Nath Decl. Ex. I (Taub Dep. at 66:9–13.)

shaped (regardless of whether they are present in a gastric cavity) and are given their form by a flexible but semi-rigid spine or scaffold:

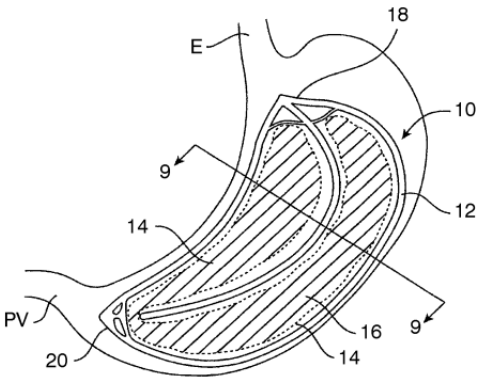


FIG. 8

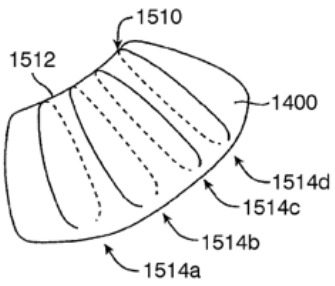


FIG. 15A

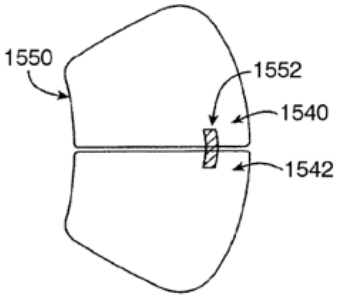
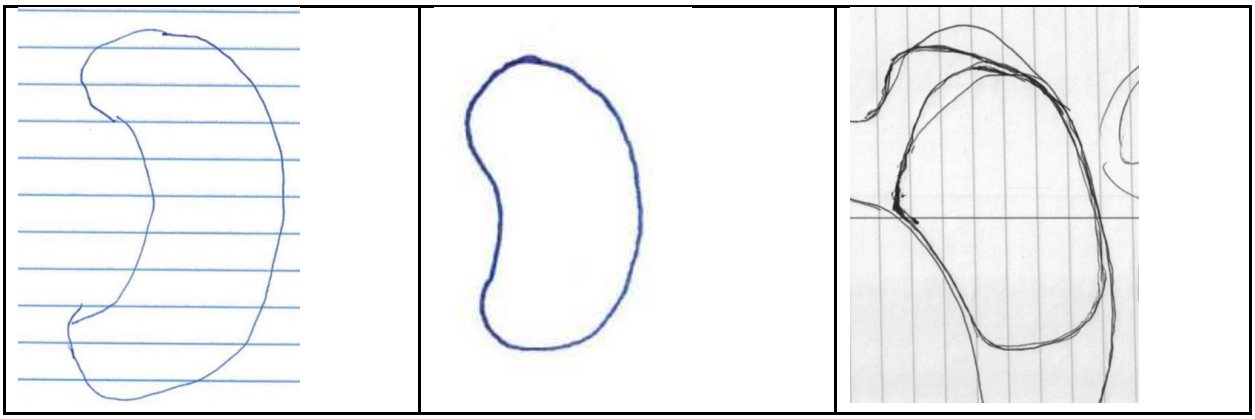


FIG. 15F

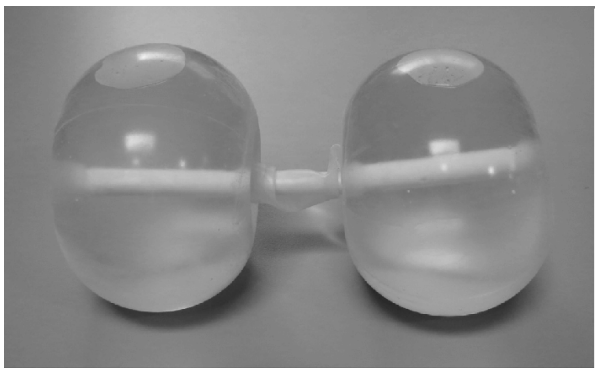
All of the inventor witnesses, when asked, confirmed the shape of a kidney as a crescent or indented oval:



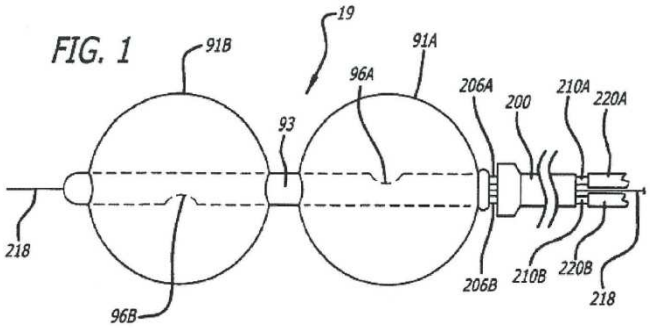
(*E.g.*, Nath Aff Ex. F (kidney shape drawing); *Id.* Ex. G (same); *Id.* Ex. H (same).) As one inventor-witness testified, a kidney shape is "a curved shape with two – two different radii define the curvature and . . . spherically capped ends." *Id.* Ex. I, Taub Dep. at 50:2–51:10. In other words, "[i]t's called a greater and lesser curvatures, referring to the kidney shape of the stomach." (*Id.* at 66:9–13.)

The Duo Balloon does not meet these "kidney shape" limitations. As shown in the images below, the Duo Balloon does not, when inflated, assume, form or otherwise have "a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity." (Birk Decl. ¶ 12.) Instead, the Duo Balloon, when

inflated fully or partially, is the shape of a barbell—two generally spherical shapes (more specifically, ovoids) with a shaft between them. (Birk Decl. ¶ 12.) It would be clear to a person of ordinary skill in the art that this shape is not curved or conforming to a kidney shape. (Birk Decl. ¶¶ 12, 19.)

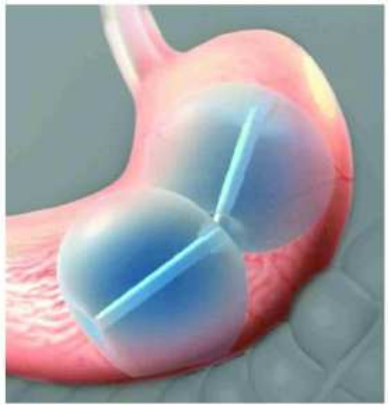


Inventor witnesses, who are POSAs, testified that a barbell shaped structure is not a "kidney shape." For example, Marc Taub testified that the following image of a barbell-shaped structure does not resemble a kidney shape:



(Nath Decl. Ex. J; Nath Decl. Ex. I, Taub Dep. at 60:10–61:12.)

Even assuming the relevant limitation requires only that the structure conforms to a kidney shape *when the structure is inserted into the stomach*, even if it does not so conform outside of the stomach, the ReShape Duo Balloon does not meet the claimed element. (Birk Decl. ¶ 20.) The structure of the device does not take the shape or outline of a kidney upon insertion into a stomach. (Birk Decl. ¶ 21.) Instead, its it takes the shape of a bent barbell when placed into a stomach, as shown below. (Birk Decl. ¶ 21.)



Fitting into the stomach is not, as discussed above, the same as the claimed "conforming to" the shape of the stomach. Conforming requires that the device take on the same shape or outline, which the Duo Balloon does not do. (Birk Decl. ¶ 22.) Indeed, this was the very intent of Plaintiff's invention. (*See* Nath. Decl. Ex. I, Taub Dep. at 19:2–21:4 (testifying the decided shape for the Fulfillium gastric balloon invention was "a shape that matches the inner anatomy of the stomach, yes. Tried to approximate the internal physiology of the stomach," which they described as "kidney shape"); *id.* at 66:5–13 (defining "kidney shape" in '915 specification to mean the same).) And, in any case, when a claim requires conforming to a shape, being capable of doing so is not sufficient to meet the limitation. *See Plantronics, Inc. v. Aliph, Inc.*, No. C 09-01714 WHA, 2014 WL 789115, at *2-3 (N.D. Cal. Feb. 26, 2014) (rejecting argument that device infringes because it is "capable" of fitting within a shaped cavity because it improperly attempted to "capture all shapes of [the device]… creating "a vagueness problem," i.e., "no one would know in advance for sure what infringes.").

Additional claims in each patent disclose that the device or each of its chambers "aligns" or "is configured to align" "against greater and lesser curvatures of the" gastric cavity or stomach. (*See* Nath Decl. Ex. A, at Claim 5b; *id.* Ex. B, at Claim 1e, 5b, 8b; *id.* Ex. C, at Claim 12b.) As one of the inventors of the Patents-in-Suit testified, "greater and lesser curvatures" "refer[s] to the kidney shape of the stomach." (Nath Decl. Ex. I, Taub Dep. at 66:9–13.) The plain and ordinary meaning of "aligns" is to bring lines or curves in line or parallel with. (Birk Decl. ¶ 23.) Thus, the device

or its chambers must be brought into parallel with the stomach. (Birk Decl. ¶ 24.) As with the kidney shape limitations, the ReShape Duo Balloon barbell structure may make spot contact with the surface of the gastric cavity but is not brought into parallel with the cavity. (*Id.*)

2. Reshape Does Not Infringe any Claims that Claim a "Chamber."

Claim 1 of the '915 Patent and the '367 Patent, as well as their respective depending Claims, all encompass an inflatable "chamber." (*See* Nath Decl. Exs. A, C; *see also id.* Ex. A, at Claim 5–7, 9, 11; *id.* Ex. B, at Claim 5; *Id.* Ex. C, at Claims 5–7, 12.) The term chamber is not otherwise defined in the claims. The specification refers to a chamber once, teaching that chambers are something "within" other inflatable structures—the scaffold, space-filling compartment(s), structure(s), or external bladder(s). (Nath. Decl. Ex. A, at 12:32–35; *id.* Ex. B, at 12:32–35; *id.* Ex. C, at 12:50–53.) Without this specification language, there is not enough information to tell a POSA what a chamber is. Thus, a "chamber" must be something "within" another inflatable structure consistent with the specification. (Birk Decl. ¶ 25.)

Plaintiff, however, points to the same structures for "chamber" and "compartment" (and also "region") in its infringement contentions. (Nath Decl. Ex. D, at Exs. A–C to Interrog. Resp. 8.) This violates the doctrine of claim differentiation, under which is a presumption that "different words or phrases used in separate claims . . . have different meanings and scope." *Karlin Tech. Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971–72 (Fed. Cir. 1999). It is presumed that two independent claims have different scope when different words or phrases are used in those claims. *See Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1365–69 (Fed. Cir. 2000).

The Duo Balloon does not have a "chamber" as disclosed in the specification because it has no compartments or other structures containing a chamber. (Birk Decl.

¶ 26.) Instead, it has two, single-layer balloons that are injection molded. (*Id.*) Neither of these balloon structures is or contains within it a "chamber." (*Id.*)

3. ReShape Does Not Infringe Claim 1 of the '915 Patent because Fluid Volume is Not Selected Based Stomach Dimensions.

The Duo Balloon also does not meet the limitation of Claim 1 disclosing "a respective fluid volume for filling each chamber of the at least two isolated non-concentric inflatable chambers is selected based upon dimensions of the gastric cavity of the patient." (Nath Decl. Ex. A, at Claim 1g; *see id.* at 12:65–13:16, 19:25–27 ("After introducing a gastroscope G, the size of the stomach can be estimated and a balloon of an appropriate size selected").) The Claim requires the stomach to be measured before selecting an appropriate volume or dimensions such as length or width for the chambers. (Birk Decl. ¶ 27.) Claim 20 of the '930 Patent similarly requires such a measurement of the gastric cavity, claiming a gastric device configured to leave a "residual volume" in the gastric cavity—*i.e.*, the volume of the stomach not filled with the gastric balloon—that is 10 ml to 100 ml. (*Id.* ¶ 28.)

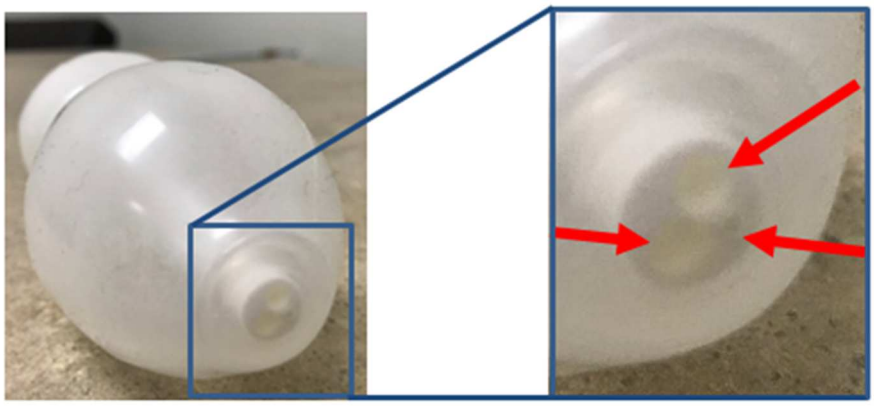
No measurement of the size or dimensions of the stomach are taken in relation to the ReShape Duo Balloon or the volume of its two balloons. (Birk Decl. ¶ 29.) As the ReShape instruction manuals provide, the balloons should each be filled to a maximum of 450cc of saline. (*Id.*; *see*, e.g., Nath Decl. Ex. K, at 9–10.) The only measurement related to balloon size considered is the height of the patient, with 375cc being used for patients under five feet four inches (64.5 inches) and 450cc being used for patients at or above five feet four inches. (*See*, *e.g.*, Nath Decl. Ex. L, at ReShape0039938; Birk Decl. ¶ 29.) Uncontested witness testimony confirms this fact. (*See*, *e.g.*, Nath Decl. Ex. N, Delagardelle Dep. at 146:11–22 (testifying that less volume is more effective for people under 5'4").) The height of the patient is not in fact indicative of the size or shape of the gastric cavity, so reliance upon height is not a measurement of the stomach. (Birk Decl. ¶ 29.)

4. ReShape Does Not Infringe Claim 16 of the '367 Patent Because the Accused Product Does Not Meet All of the Claimed Limitations.

Plaintiff's infringement claims as to Claim 16 of the '367 Patent, and the asserted depending Claims 17–21, fail because Plaintiff cannot establish that the ReShape Duo Balloon meets two of the claim limitations.

a. The Accused Device Remains Connected to a Lumen.

First, the Duo Balloon does not meet Claim 16e: "wherein the dual-balloon system is configured to float freely in the patient's stomach and is not connected to any catheter, lumen or tether after deployment in the patient's stomach." (Birk Decl. ¶ 30.) The ReShape Duo Balloon has three "lumens" inside the shaft that connects the two balloons. (*Id.*) Two of the lumens are used to inflate each balloon, respectively. (*Id.*; Nath Decl. Ex. O, Youngstrom Dep. at 99:13–25.) The third lumen is used to allow the insertion of a guidewire that assists with placing the device in a patient's stomach. (Birk Decl. ¶ 30.) After deployment into a patient's stomach, the Duo Balloon remains "connected" to those lumens, as they remain within the shaft of the device at all times. (*Id.*) As such, the Accused Product does not meet this claim limitation and Plaintiff's infringement claim as to Claim 16 of the '367 Patent, and its depending Claims, fails.



b. The Accused Device Is Not Configured To Rest Within The Gastric Cavity Without Exerting Any Pressure At Any Point In The Gastric Cavity Sufficient To Cause Abrasion, Pressure Induced Lesions, Or Other Trauma.

Second, the ReShape Duo Balloon does not meet the claim limitation claiming a device "configured to rest within the gastric cavity without exerting any pressure at any point in the gastric cavity sufficient to cause abrasion, pressure induced lesions, or other trauma." (*See, e.g.*, Nath Decl. Ex. A, at Claim 16). "Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014) (*citing Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 65–66 (1923)). Thus, when a term of degree is used in the claim, the examiner should determine whether the specification provides some standard for measuring that degree. *Hearing Components, Inc. v. Shure Inc.*, 600 F.3d 1357, 1367 (Fed. Cir. 2010); *Enzo Biochem, Inc., v. Applera Corp.*, 599 F.3d 1325, 1332 (Fed. Cir. 2010). If the specification does not provide some standard for measuring that degree, a determination must be made as to whether one of ordinary skill in the art could nevertheless ascertain the scope of the claim (e.g., a standard that is recognized in the art for measuring the meaning of the term of degree). For example, in *Ex parte Oetiker*, 23 USPQ2d 1641 (B.P.A.I. 1992), the phrases "relatively shallow," "of the order of," "the order of about 5mm," and "substantial portion" were held to be indefinite because the specification lacked some standard for measuring the degrees intended.

Here, he specification teaches the "inflated device/dual balloon system weighs between 50 gm and 500 gm and has a fluid with a specific gravity of .09 to .05 and a ration of air:liquid of 2:1 to 10:1." (Nath Decl. Ex. C, at 10:27–53; Birk Decl. ¶ 31.) This is the only language that informs the range of pressure required to meet the

definiteness requirement. (*Id.*) Without it, a POSA would not be able to ascertain the scope of the claim. (*Id.*) Assuming that this construction applies to the Claim limitation, the ReShape Duo Balloon does not meet the limitation because Plaintiff has not presented any evidence that the device falls within this range. (*Id.*) Moreover, the Duo Balloon does not meet the air to liquid ratio requirement of the Claim because it is not filled partially with air and partially with liquid. Instead each balloon is filled solely with a liquid saline. (*Id.*; Nath Decl. Ex. O, Youngstrom Dep. at 100:16–22.) Finally, the Duo Balloon does not meet the limitation because, as ReShape's expert Janel Birk confirms, the device does, in fact, exert pressure sufficient to cause ulcers, and other abrasions, pressure induced lesions, or other trauma, and has in some instances, at low rates, caused these in patients that used the ReShape Duo Balloon. (Birk Decl. 32.)

V. CONCLUSION

Because Plaintiff cannot establish direct or indirect infringement of the Patents-in-Suit, Defendants respectfully request that the Court grant this motion for summary judgment of non-infringement.

Dated: July 9, 2019

Respectfully submitted,

FOX ROTHSCHILD LLP

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Larina A. Alton (*pro hac vice*)

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